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- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

(54) Title: **MYCOPLASMA GALLISEPTICUM FORMULATION**

(57) Abstract: The present invention provides a protective formulation that prevents virulent *Mycoplasma gallisepticum* infection in birds of the order Galliformes. The formulation comprises a protective amount of live MG strain K5054 or derivatives thereof in a pharmaceutically acceptable carrier. A vaccine that prevents virulent *Mycoplasma gallisepticum* infection in birds of the order Galliformes is also presented. Methods for administering the formulation and vaccine are also presented.

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/22011

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61K 39/38, 39/385, 39/02
 US CL : 424/184.1, 192.1, 234.1, 264.1

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 424/184.1, 192.1, 234.1, 264.1

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
 Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|--|-----------------------|
| Y | US 5,766,594 A (KODAMA et al.) 16 June 1998 (16.06.1998), see entire document. | 1-65 |
| Y | US 5,621,076 A (KODAMA et al.) 15 April 1997 (15.04.1997), see entire document. | 1-65 |
| Y | US 5,489,430 A (SAITO et al.) 06 February 1996 (06.02.1996), see entire document. | 1-65 |
| Y | EP 0 603 406 A1 (NIPPON ZEON CO., LTD.) 28 May 1993 (28.05.1993), see entire document. | 1-65 |
| Y | US 5,004,607 (RAGLAND et al.) 02 April 1991 (02.04.1991), see entire document. | 1-65 |

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"B" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T"

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X"

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y"

document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&"

document member of the same patent family

Date of the actual completion of the international search

08 December 2003 (08.12.2003)

Date of mailing of the international search report

29 DEC 2003

Name and mailing address of the ISA/US

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INTERNATIONAL SEARCH REPORT

International application No.

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Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claim Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claim Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claim Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
Please See Continuation Sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐
☐

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I, claim(s) 1-4, 25-29 and 50-62, drawn to protective formulations (vaccines) for birds of the order Galliformes comprising a *Mycoplasma gallisepticum* bacterial strain having a RAPD pattern substantially corresponding to at least one of the band pattern of K5054 deposited at the ATCC with the designation PTA-4507 and methods of using said compositions to immunize birds of the order Galliformes.

Group II, claim(s) 5-8 and 30-32, drawn to protective formulations (vaccines) for birds of the order Galliformes comprising a *Mycoplasma gallisepticum* bacterial strain having a RAPD pattern substantially corresponding to at least two of the band patterns of K5054 deposited at the ATCC with the designation PTA-4507.

Group III, claim(s) 9-12 and 33-36, drawn to protective formulations (vaccines) for birds of the order Galliformes comprising a *Mycoplasma gallisepticum* bacterial strain having a RAPD pattern substantially corresponding to three band patterns of K5054 deposited at the ATCC with the designation PTA-4507.

Group IV, claim(s) 13-16 and 37-40, drawn to protective formulations (vaccines) for birds of the order Galliformes comprising a *Mycoplasma gallisepticum* bacterial strain having a PVP surface adhesin gene with a nucleotide sequence with at least 98% homology to SEQ ID NO:1.

Group V, claim(s) 17-20 and 41-44, drawn to protective formulations (vaccines) for birds of the order Galliformes comprising a *Mycoplasma gallisepticum* bacterial strain having a surface lipoprotein gene with a nucleotide sequence with at least 98% homology to SEQ ID NO:2.

Group VI, claim(s) 21-24, 45-49 and 63-65, drawn to protective formulations (vaccines) for birds of the order Galliformes comprising a *Mycoplasma gallisepticum* bacterial strain K5054 deposited at the ATCC with the designation PTA-4507 and methods of using said compositions to immunize birds of the order Galliformes.

Group VII, claim(s) 63, drawn to methods of immunizing birds of the order Galliformes against utilizing *Mycoplasma gallisepticum* utilizing a non immunopathogenic *Mycoplasma gallisepticum* strain.

The inventions listed as Groups I- VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Pursuant to 37 C.F.R. 1.475(d), the ISA/US considers that where multiple products and processes are claimed, the main invention shall consist of the first invention of the category first mentioned in the claims and the first recited invention of each of the other categories related thereto. Accordingly, the main invention (Group I) comprises the first recited product, protective formulations (vaccines) for birds of the order Galliformes comprising a *Mycoplasma gallisepticum* bacterial strain having a RAPD pattern substantially corresponding to at least one of the band pattern of K5054 deposited at the ATCC with the designation PTA-4507 and methods of using said compositions to immunize birds of the order Galliformes. Further pursuant to 37 C.F.R. 1.475(d), the ISA/US considers that any feature which the subsequently recited products and methods share with the main invention does not constitute a special technical feature within the meaning of PCT rule 13.2 and that each of such products and methods accordingly defines a separate invention.

The special technical feature of Groups I-VII are the strains of *Mycoplasma gallisepticum*, each of which constitute a patentably distinct entity with differing physical, biological and immunological properties.

INTERNATIONAL SEARCH REPORT

PCT/US03/22011

Continuation of B. FIELDS SEARCHED Item 3:
EAST, MEDLINE, CAPLUS, BIOSIS

search terms: mycoplasma, gallisepticum, galliformes, vaccine, antigen, antigenic protein